

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

IN RE: MARSHALL, WILLIAM E.)	
)	APPEAL NO. _____
SERIAL NO: 09/883,550)	
)	
FOR: METHODS AND COMPOSITIONS)	
FOR MODULATING IMMUNE SYSTEMS)	BRIEF ON APPEAL
OF ANIMALS)	
)	
FILED: JUNE 18, 2001)	
)	
GROUP ART UNIT: 1638)	

To Commissioner for Patents
Mail Stop Appeal Brief – Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs and Madams:

In response to the Notification of Non-Compliant Appeal Brief dated March 1, 2007, please find attached Section VIII Claims Appendix. Applicants believe that they are in compliance with 37 CFR 41.37(c)(1)(v) and request that this be entered.

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Respectfully submitted,



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VIII. CLAIMS APPENDIX

1. A method for modulating the immune system of an animal comprising:
growing bacteria in a medium;
exposing said bacteria to biological, chemical or physical stress for at least two or more sequential periods of stress wherein each period of stress is defined by a period of stress exposure of approximately 20 minutes or less so that the bacteria release a stress response product comprising stress response factors (SRFs);
separating said medium and SRFs from said bacteria to form a separated product;
filtering said separated product to remove substances having a molecular weight of greater than 10kDa to form a filtrate; and
administering said filtrate to said animal.
4. The method of claim 1 wherein said medium comprises a non-nutritive saline media at pH values of 6.0 to 8.0.
5. The method of claim 4 wherein said saline media is a phosphate-buffered saline having a pH of about 7.0.
6. The method of claim 1 wherein the bacteria are selected from the group consisting of Lactobacillus, Staphylococcus, Streptococcus, Pediococcus, Pseudomonas, Bacillus, Escherichia, Listeria, Enterococcus, and Klebsiella.
7. The method of claim 6 wherein the bacteria are selected from the group consisting of *L. acidophilus*, *L. caseii*, *L. fermentum*, *L. plantarum*, *L. monocytogenes*, *S. aureus*, *S. typhimurium*, *P. acidolactici*, *B. coryneforme*, *E. coli*, *E. faecium*, *S. pyogenes*, and *K. pneumoniae*.
8. The method of claim 1 wherein the bacteria are propagated at a temperature ranging from approximately 22°C to approximately 37°C.

10. The method of claim 1 wherein the bacteria are exposed to a stress while they are in the stationary phase of their life cycle.
11. The method of claim 1 wherein the filtering step includes:
passing said separated product through a 0.22 µm filter to form a sterilized product; and
passing said sterilized product through a filter with a molecular weight cutoff of 10 kDa.
12. The method of claim 1 wherein the filtrate containing the stress response factors (SRFs) with a molecular weight less than 10kDa is administered to an animal selected from the group consisting of humans, poultry and livestock.
14. The method of claim 1 wherein the stress response product is administered in a manner selected from the group consisting of orally, topically, and parenterally.
15. The method of claim 1 wherein the animal is administered stress response products having a weight of between 0.5 and 3 kDa.
16. The method of claim 1 wherein the stress response products are administered as an adjuvant for oral or parenteral vaccines.
17. The method of claim 1 wherein the bacteria are exposed to at least two or more sequential periods of stress wherein each period of stress is approximately 10-20 minutes.
18. The method of claim 17 wherein the bacteria are exposed to sequential periods of stress by transferring the bacteria from growth media into non-nutritive media in the initial period of stress, then subsequently transferring the bacteria to non-nutritive media in the sequential periods of stress.
19. The method of claim 18 wherein the bacteria are exposed to three sequential periods of stress.